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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,959	06/19/2000	Lennart Lindfors	1103326-0623	6637

7590

06/18/2002

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/581,059**

Applicant(s)  
**Lindfors et al.**

Examiner  
**Zohreh Fay**

Art Unit  
**1614**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36, 40-42, 45, and 46 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36, 40-42, 45, and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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Claims 1-36, 40-42, 45 and 46 are presented for examination.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 30-35, 45 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-10, 24 and 25 of U.S. Patent No. 6,372,728. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap. The claims of the instant application

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are drawn to a markush group of different additive and a biphosphonate. The additives overlap with the additive used in the claims of the parent application.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 12, 13, 14, 29-42 and 45-46 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 88/00829. The WO Patent teaches the use of the claimed biphosphonate in combination with the claimed additive for the treatment of osteoporosis.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 8-11, 15-28 and 47 are rejected under 35 U.S.C. 103 as being unpatentable over WO 88/00829 and Fuches et al. (U.S. Patent 5,759,586).

WO Patent teaches the use of biphosphonic acid in combination with additives for the treatment of osteoporosis. See page 5, lines 11-40, page 6 lines 1-21 and claims 1-6. Fuches et al. Teach the use of biphosphnates for the treatment of osteoporosis. See page 4 lines 13 and 14. The addition of additive glycerophosphate to a composition used for the treatment of osteoporosis is also taught by the above reference. See page 7, line 11. The above references

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differ from the claimed invention in using the combination of additives or a specific additives. To incorporate such teachings into the above references would have been obvious to a person skilled in the art, considering that such additives are well known in the pharmaceutical art and the use of such agents individually or in combination is old in the pharmaceutical preparations. One skilled in the art would have been motivated to employ the teachings of the above references, since they relate to the use of a bisphosphonate in combination with an additive for the treatment of osteoporosis. The substitution of one additive for another would have been obvious to a person skilled in the art in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, the above claims are rejected under 35 U.S.C. 103.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Fay whose telephone number is (703) 308-4604.

ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1200

